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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/007,268	01/14/1998	JOHN A. LOWE, III	PC7981C	4701

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/007,268	LOWE, ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2003 and 06 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33 and 36-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33 and 36-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Action

The following is responsive to Applicant's amendment and letter received Jan. 27, 2003 and March 6, 2003.

No claims are cancelled. No new claims are added. Claims 33, 36-62 are currently pending.

The previous claims rejection under 35 USC 112, paragraph 2, set forth in paragraph 1 of the office action mailed July 16, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, upon further consideration of the pending claims with the Supervisory Patent Examiner, several issues were discovered and are addressed below.

The allowability of the claims 33, 36-57, 60-62 is withdrawn in view of the new ground of rejection submitted below.

New Ground(s) of Rejection

Claim Rejections - 35 USC § 112

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is drawn to "a method of treating or preventing a condition in a mammal, the treatment or prevention of which is affected or facilitated by a decrease in Substance P mediated neurotransmission" by administering an effective amount of the composition according to claim 33.The claimed method of treatment or prevention fails to meet the requirement for an adequate written

description of the claimed invention as required by 35 USC, 112, paragraph 1.There is insufficient descriptive support for the generic limitation "a condition in a mammal, the treatment or prevention of which is affected or facilitated by a decrease in Substance P mediated neurotransmission." Furthermore, the claimed methods require treatment of an unspecified disease and no evidence indicates that treatable diseases, other than those listed in the specification (page 15, line 23 to page 16, line 31), were known to Applicant. In the absence of some further understanding of other diseases to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed method.

Claims 33, 36, 39-57, 58, 59, 60-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to "a method of treating or preventing a condition selected from the group consisting of ....stress related somatic disorders, neuropathological disorders, fibrosing and collagen diseases, hypersensitivity disorders and disorders related to immune enhancement or suppression" by administering an effective amount of the composition comprising the compound of Formula I. The claimed methods of treatment or prevention fail to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1.There is insufficient descriptive support for the generic limitations "stress related somatic disorders, neuropathological disorders, fibrosing and collagen disorders,

hypersensitivity disorders and disorders related to immune enhancement or suppression" Furthermore, the claimed methods require treatment of unspecified diseases and no evidence indicates that treatable diseases, other than those listed in the specification (page 15, line 23 to page 16, line 31), were known to Applicant. In the absence of some further understanding of other diseases to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed methods.

35 USC 112, paragraph 1—Enablement

Claims 33, 36, 38-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to a method of treating or preventing numerous conditions/disease in a mammal comprising administering an effective amount of a compound represented by formula I.

(2) The state of the prior art

While the art recognizes the treatment of neuropathological disorders such as Alzheimer's disease, the art does not recognize, however, therapeutic remedies which result in the complete prevention of said diseases. Furthermore, the art may recognize the treatment of most of the numerous disorders claimed; however, prevention of most of the disorders such as immune disorders, psychosis, other neuropathological disorders, i.e. Parkinson's diseases, etc. have yet to be recognized.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and chemical art is high.

(5) The breadth of the claims

The claims are very broad and encompass treatment of numerous diseases and conditions.

(6) The amount of direction or guidance presented

Applicant's specification does not appear to provide guidance for the treatment and prevention of all the claimed diseases and conditions. The specification provides no guidance to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims, which, as stated above, are broad and encompass numerous

disorders. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." Applicant's specification does not set forth a representative number of examples of diseases or disorders, which the claimed compounds would be capable of treating or preventing.

(7) The presence or absence of working examples

There are no working examples, in vivo or in vitro, in the specification relating to the treatment or prevention of any of the claimed diseases or disorders. The specification provides examples directed to preparing the compounds encompassed by the claims. The only "working example" disclosed is at pages 34-35, where Applicant describes a radioligand binding procedure to study the ability of the claimed compounds to inhibit the binding of Substance P to receptor sites in bovine caudate tissue. Then at page 35, lines 11-25, Applicant describes that the neuroleptic acitivty of the compounds may be carried out in guinea pigs by following the disclosed procedural steps.

(8) The quantity of experimentation necessary

Since (1) prevention of neuropathological diseases (Alzheimer's disease) as well as some of the other disorders claimed by Applicant has not been achieved and thus recognized in the art, and (2) since the only working example in Applicant's specification is a radioligand assay to study the inhibitory activity of the claimed compounds against

Substance P, and (3) since compound structure and activity for pharmaceutical use must be determined from case to case by painstaking experimental study, especially for each of the claimed disorders, one of ordinary skill in the art would be burdened with undue experimentation to determine the pharmacological parameters i.e. dosage, etc. necessary to enable one of ordinary skill in the art to actually prevent and/or treat the numerous diseases claimed by Applicant as well as to prevent the occurrence of neuropathological disorders, autoimmune disorders, etc.

Conclusion

Claims 33, 36-62 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER

CDM

August 13, 2003